

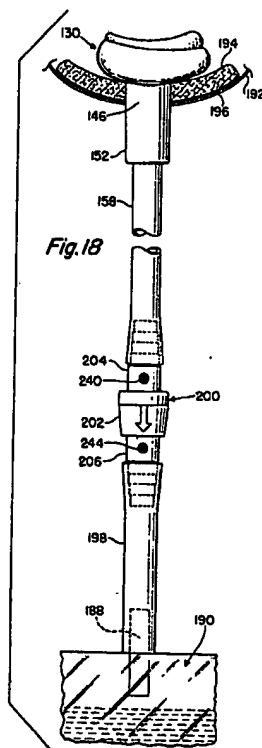
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 (71) Applicant  
 Illinois Tool Works Inc.,  
 (USA—Delaware),  
 8501 West Higgins Road,  
 Chicago,  
 Illinois 60631,  
 United States of America  
 (72) Inventors  
 Kenneth F. Hall,  
 William H. Beecher  
 (74) Agent and/or address for  
 service  
 Gill, Jennings & Every,  
 53—64 Chancery Lane,  
 London,  
 WC2A 1HN

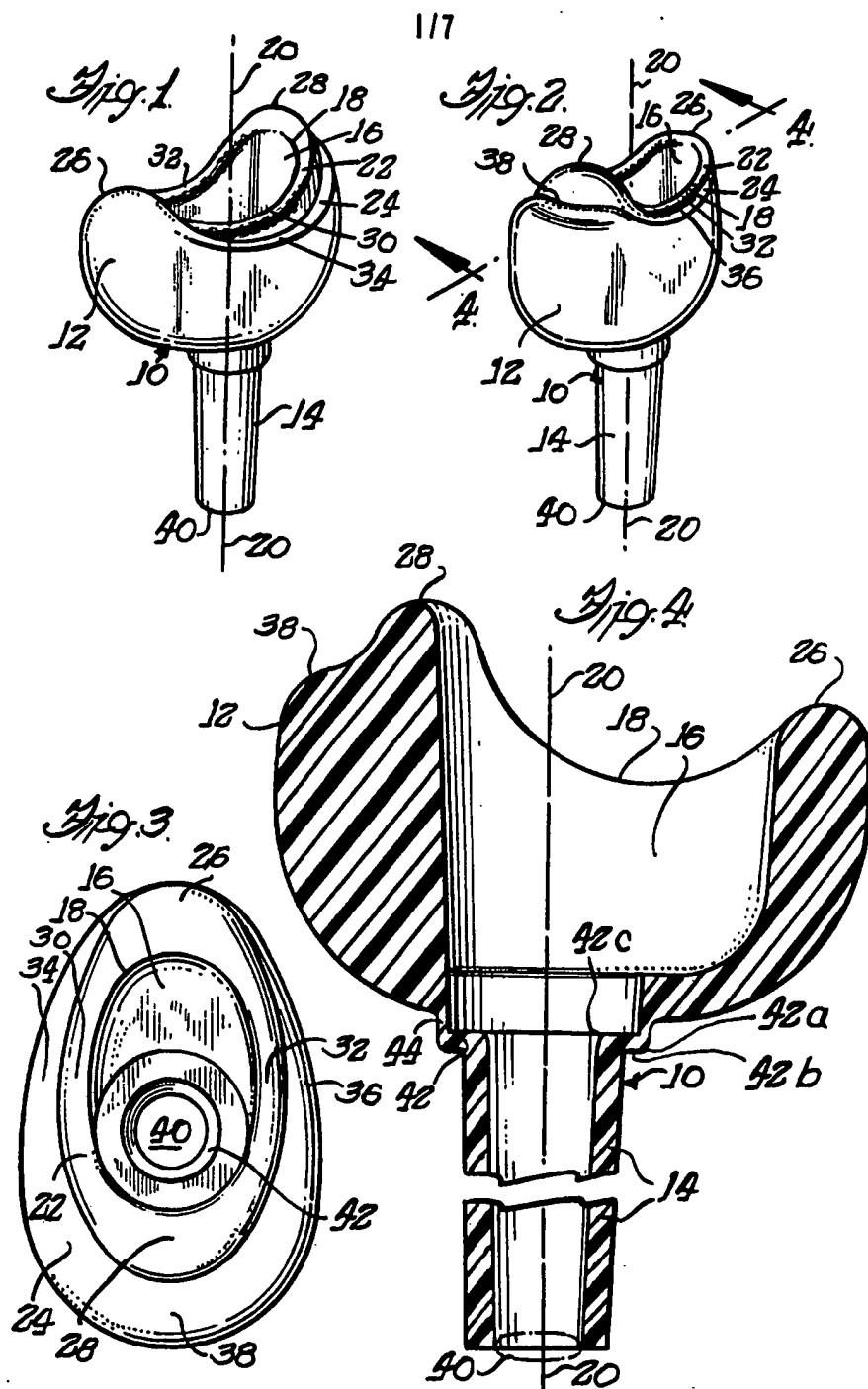
(54) Female urinary appliance

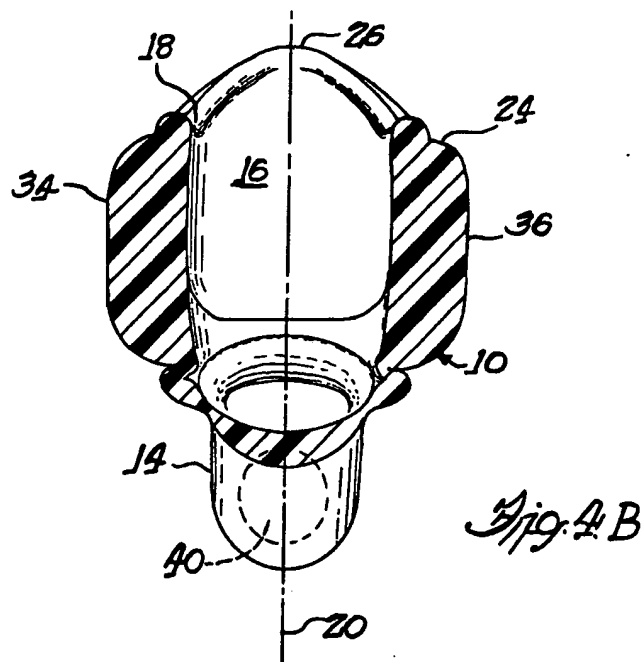
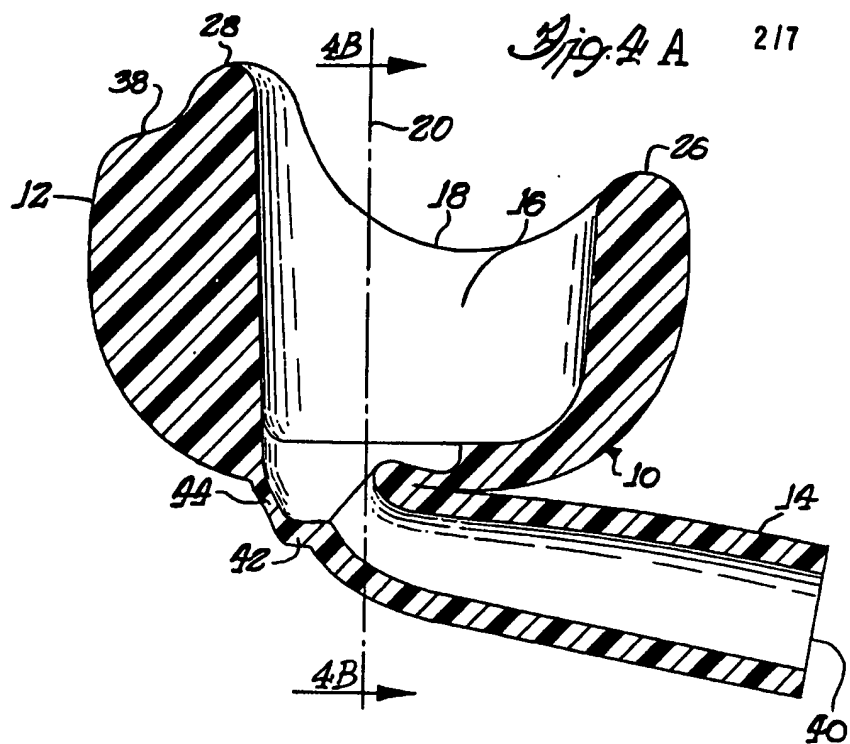
(57) An improved female urinary appliance includes a mouth surrounding a urine-receiving cavity, and a drainage channel integral with the backside of the device and communicates with a bore opening from said cavity. The device includes means for preventing the drainage channel from kinking. The mouth is adapted to be positioned within the labia folds of the user, in contact with the vestibular tissue around the meatus and held in place by gentle vacuum. A valve is preferably used in combination with the appliance, and includes an inlet and an outlet, for maintaining a preselected vacuum condition at the valve inlet and a

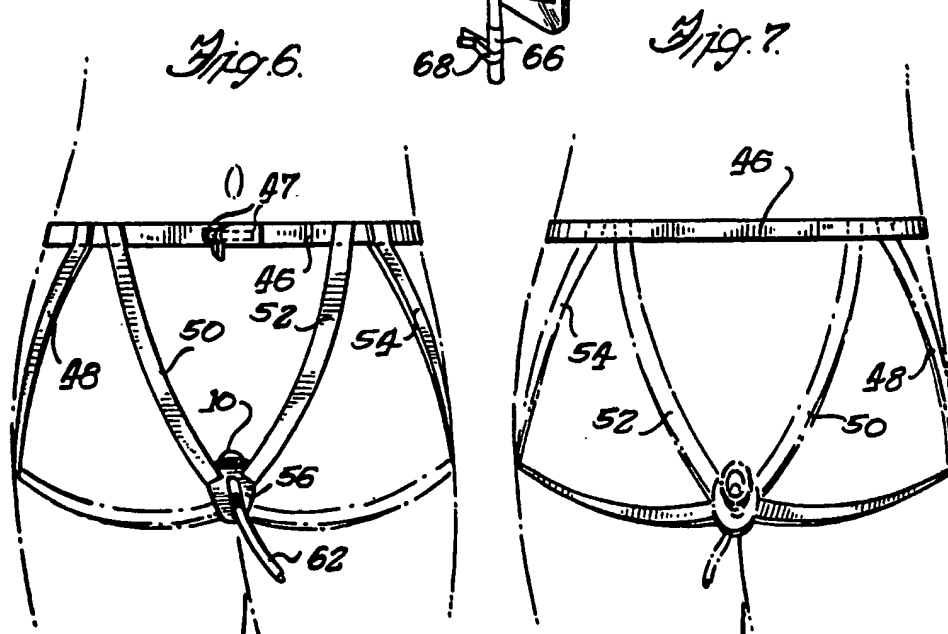
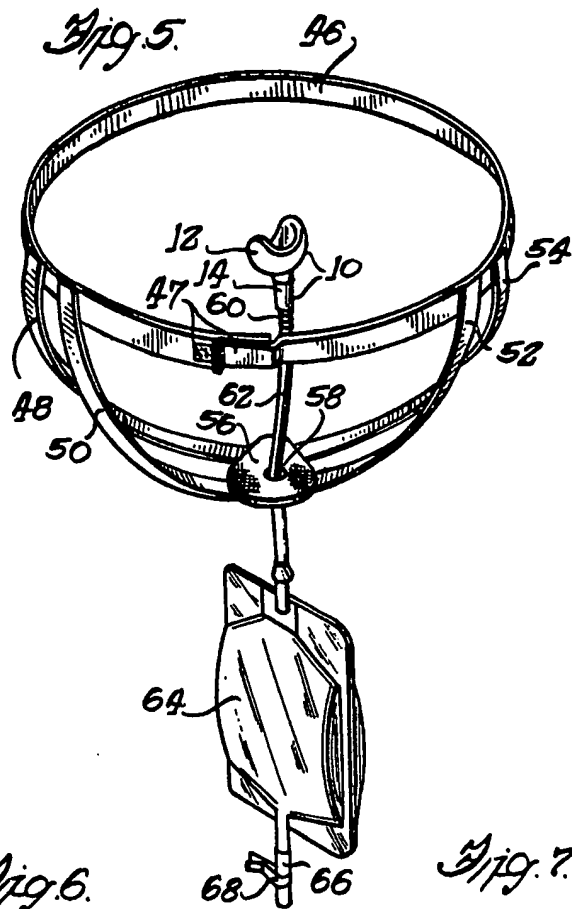
predetermined pressure condition at the valve outlet is disclosed. In preferred use, the drainage channel is suitably connected in spaced relation to the valve inlet. The valve contains a flow control element adapted to control flow of urine from the cavity. While the mouth is held against the vestibular tissue by gentle vacuum, urine flowing through the appliance and valve entrains gas present in the cavity. In the cavity, a desired vacuum condition is maintained, over time, because the valve includes a semi-permeable membrane adapted to permit air and other gas to diffuse through a portion of the valve and thereby to counteract the effects of entrainment and relieve or maintain the vacuum condition at a predetermined level.

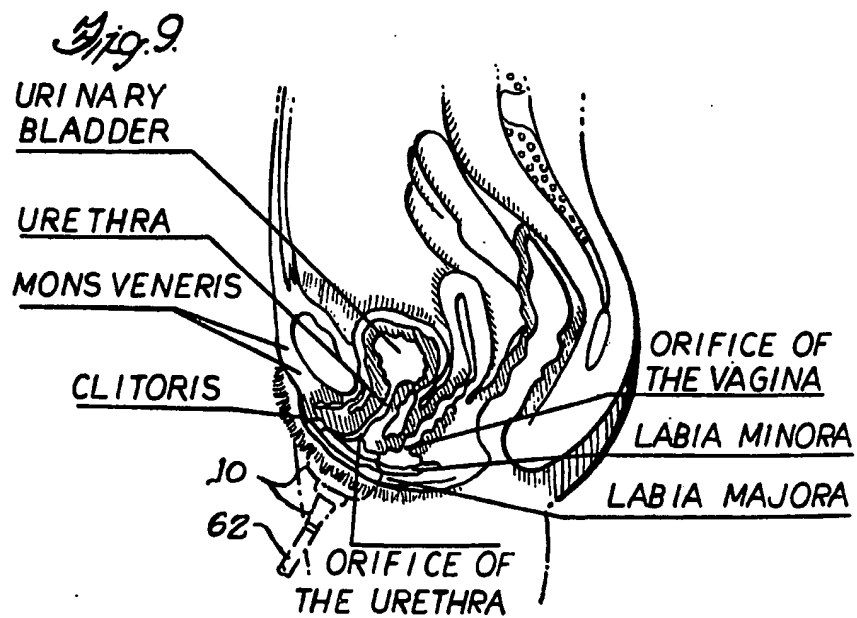
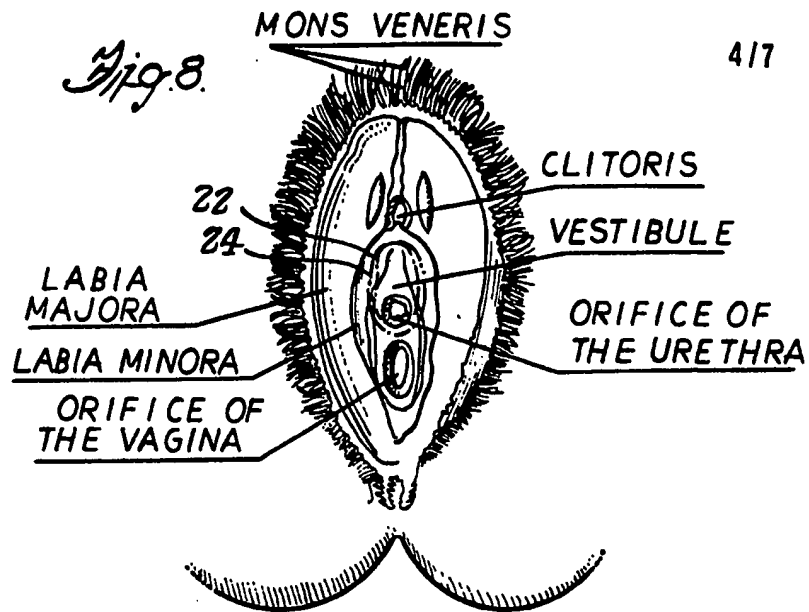


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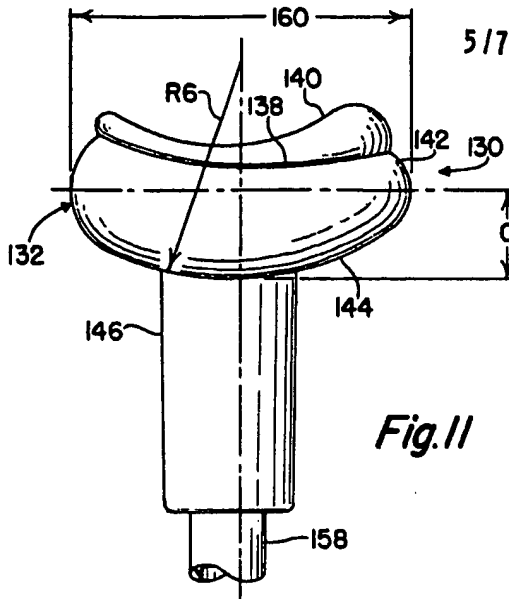
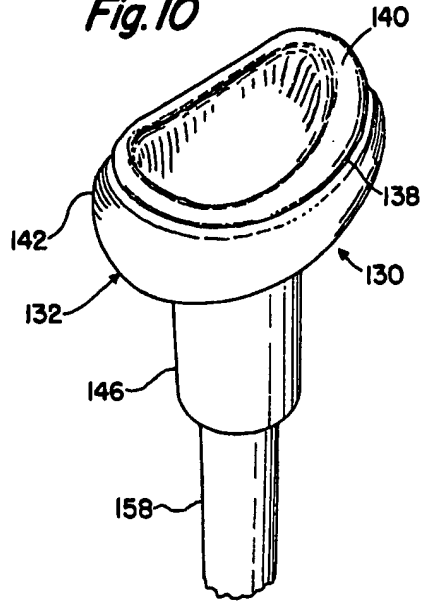




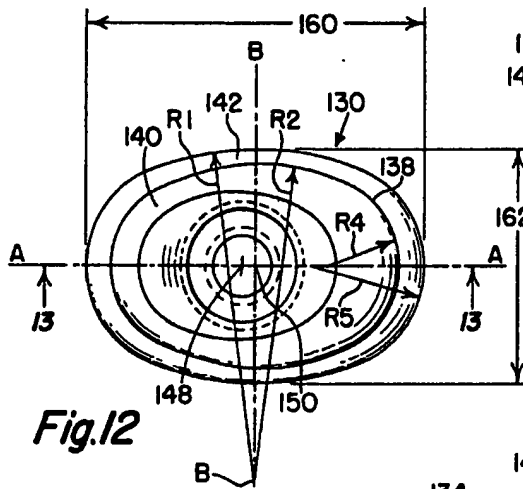




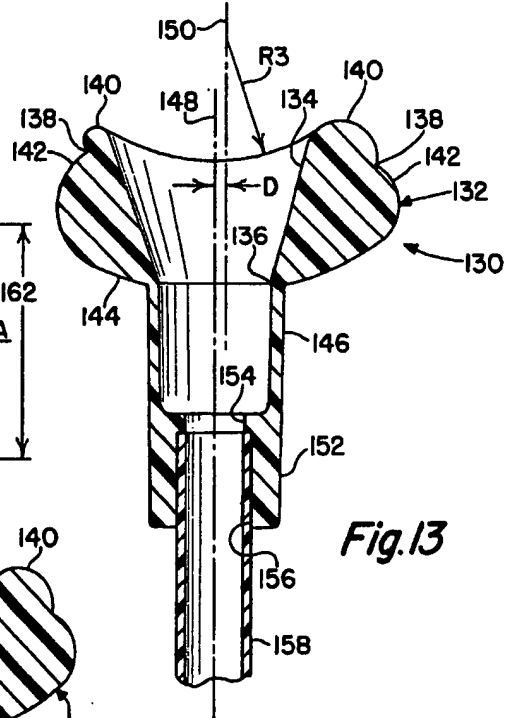
*Fig. 10*



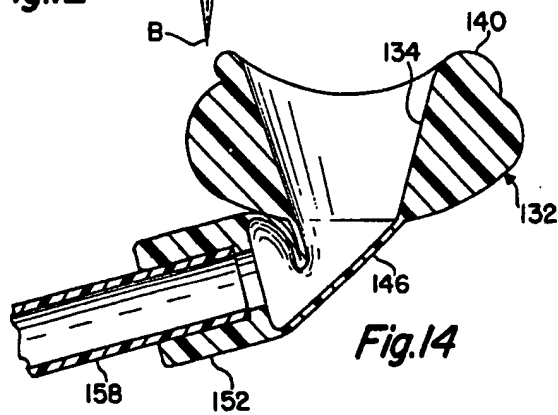
*Fig. 11*



*Fig. 12*



*Fig. 13*



*Fig. 14*

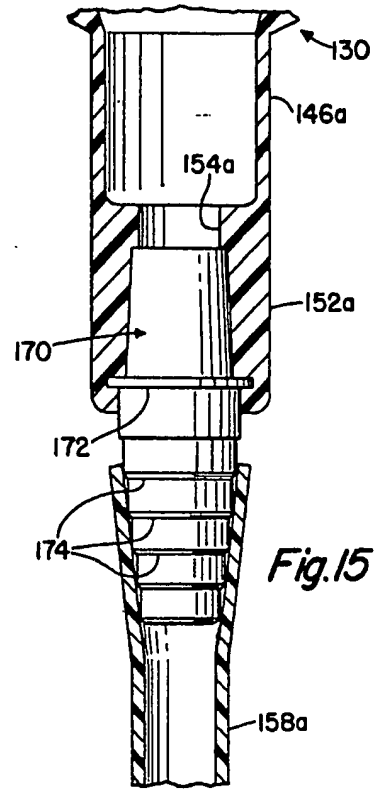
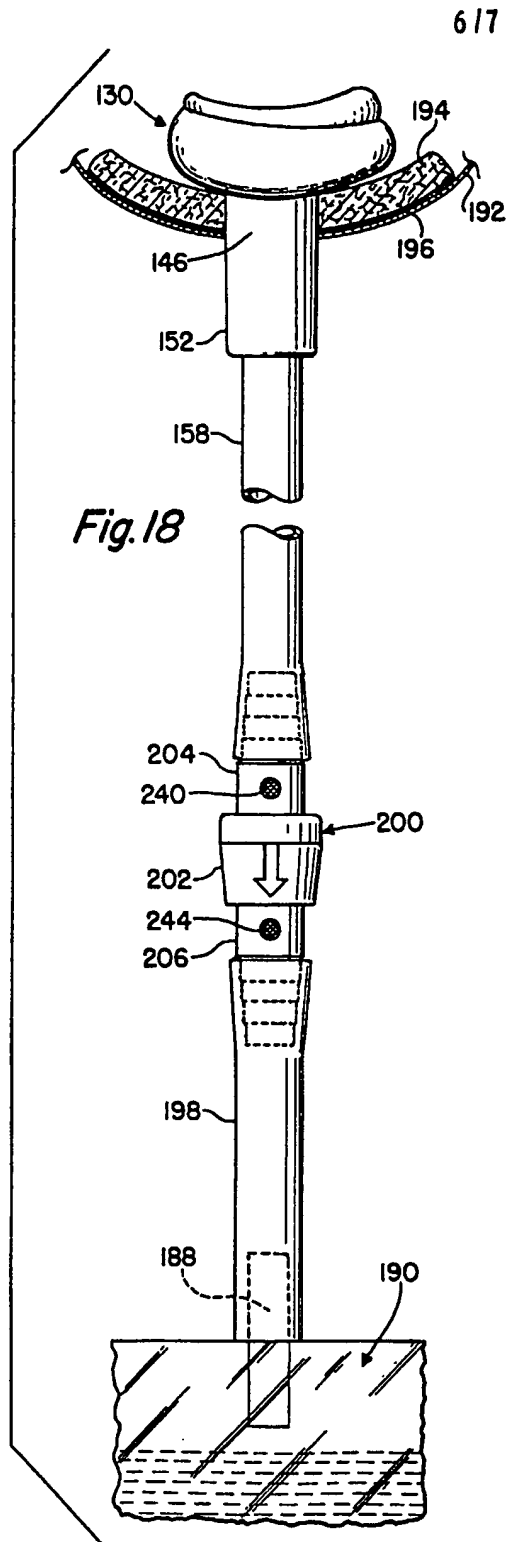


Fig. 16

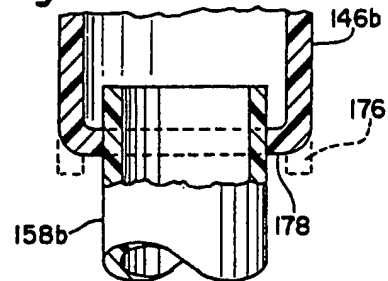
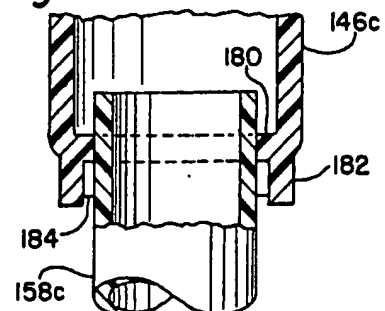
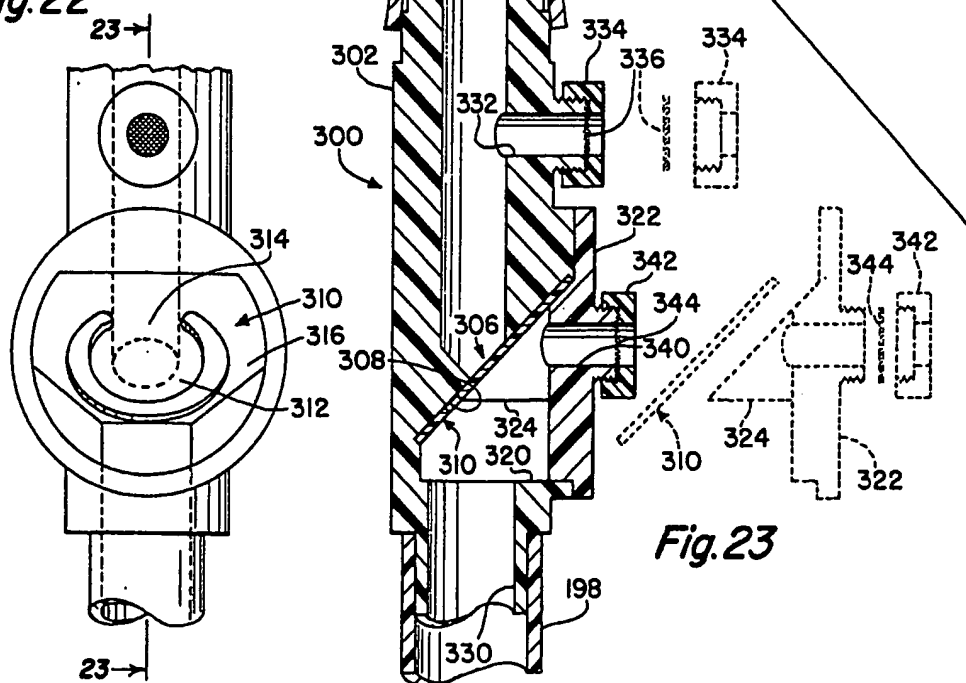
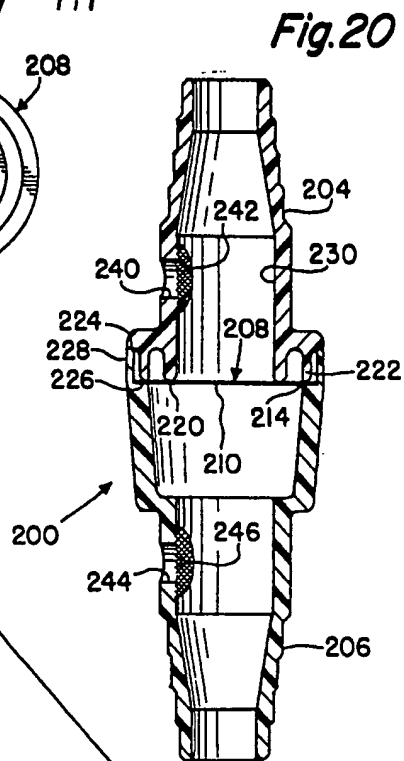
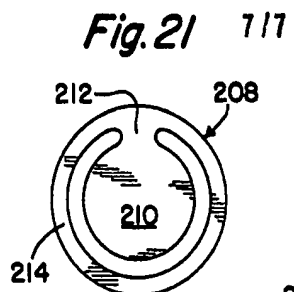
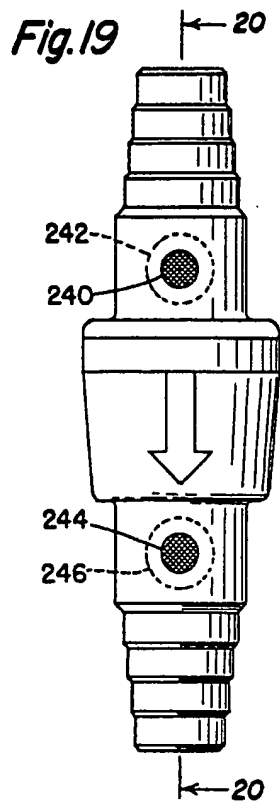


Fig. 17







## SPECIFICATION

## External female urinary appliances

## Background of the invention

This invention relates to a field of human  
 5 urinary appliance or devices which have been  
 adapted to be held in place exterior to the human  
 form; and more particularly, this invention relates  
 to a field of urinary appliances which have been  
 specifically adapted to be gently held in place  
 10 essentially exterior to the female human form. The  
 appliance has been found effective when used by  
 a subject who is in an upright, sitting, or generally  
 supine position.

Certain paraplegic, quadriplegic, incontinent,  
 15 and other female human subjects often require  
 assistance when relieving the urinary bladder of  
 urine. The female urinary appliance industry  
 manufactures a variety of devices adapted to  
 provide different degrees of assistance to such  
 20 subjects. One problem the female urinary  
 appliance industry faces is manufacture of an  
 appliance which is easily worn and which does  
 not leak when in use. This essentially means that  
 the appliance must not only be capable of being  
 25 secured to the female human form by  
 commercially available securement means and of  
 being held snugly in place by such securement  
 means, but it also means that the appliance must  
 provide an effective and otherwise non-leaking  
 30 seal when applied to the female human form (or  
 outer surface of the body). In addition, these  
 appliances must be non-binding, non-pinching,  
 non-irritating, resilient, elastic, sterile, aseptic and  
 generally somewhat smooth and soft to the  
 35 touch.

Much of the prior art has not addressed the  
 leakage problem associated with bodily  
 engagement of a particular urinary appliance  
 upon the female human form; and therefore,  
 40 much of the female urinary appliance prior art has  
 avoided claiming a leak-free urinary appliance. The  
 key to the leak-free feature of any female urinary  
 appliance is the way in which such appliance  
 engages the female human form.

Many of the difficulties associated with a  
 female urinary appliance making a sealing  
 engagement with the female human form  
 naturally grow out of the unique nature of the  
 external female organs of generation which, of  
 50 course, surround the orifice of the urethra.  
 Reference to Fig. 8 is herein made to illustrate  
 engagement of the appliance with generally  
 recognized female bodily surfaces.

Medical authority teaches us that the external  
 55 organs of generation in the human female are the  
 mons Veneris, the labia majora and minora, the  
 clitoris, the meatus urinarius, and the orifice of  
 the vagina; and further defines the term "vulva"  
 or "pudendum" to include all these parts. In  
 60 addition, the "vestibule", as used in connection  
 with the female human form, is medically defined  
 to be located in a triangularly shaped, smooth  
 region between the clitoris and the entrance of  
 the vagina, and bounded on each side by the labia

65 minora. Lastly, medical authority teaches us that  
 the meatus urinarius (also referred to as the  
 orifice of the urethra) is situated at a back (or  
 lower) part of the vestibule, about an inch below  
 the clitoris, near the margin of the vagina, and  
 70 that the meatus urinarius is surrounded by a  
 prominent elevation of a mucous membrane (also  
 referred to as the mucosa).

It is an object of the present invention to  
 provide a female urinary appliance which can  
 make a leak-free sealing engagement with the  
 female human form, while the subject is in a  
 standing, sitting, or generally supine position.

Accordingly, one general object of this  
 invention is to provide a system capable of  
 80 managing incontinence in females without the  
 use of indwelling catheters, diapers, etc. This is  
 accomplished by providing an improved urinary  
 appliance adapted to be sealingly engagable with  
 the female human form, such engagement being  
 85 enhanced by a vacuum or negative pressure  
 condition.

A more specific object is that a gentle vacuum  
 condition, for such an improved appliance, be  
 somewhat constant and easily maintainable at  
 90 the region where the appliance contacts and  
 surrounds the vestibular tissue.

A more specific object is to provide a system  
 including a discharge tube of predetermined  
 height and a valve which is adapted to achieve a  
 95 vacuum condition by maintaining a column of  
 liquid having a preselected and relatively  
 unvarying height.

A further object is to provide a valve which is  
 generally unaffected, in operation, by air or other  
 gas entering the valve via the valve outlet.

A related object is to provide such a valve  
 having a valve body adapted to accept a  
 hydrophobic filtered vent port which will permit  
 air or other gas to diffuse therethrough.

Yet another general object of this invention is  
 to provide an improved appliance, a valve and  
 collection system which when used together co-  
 operate to permit accomplishment of a  
 particularly useful result.

Accordingly, a more specific object is, first, to  
 provide an improved appliance which is sealingly  
 engagable, such engagement being enhanced by  
 predetermined vacuum conditions, with certain  
 vestibular tissue of the female, and second, to  
 115 provide a novel valve which provides the  
 improved appliance with the predetermined  
 vacuum condition desired.

While a multiplicity of known valve forms can  
 be utilized the preferred illustrative embodiments  
 120 are flapper type valves which require a  
 predetermined head for operating the device and  
 which are in a normally closed position. In one  
 illustrative embodiment there are two filtered vent  
 ports which include a hydrophobic filter that  
 permits diffusion of gas therethrough but not  
 liquids. In a preferred system that includes eight  
 inches of vertical tubing between the appliance  
 and the anti-reflux valve the following  
 125 pressure/vacuum sequence occurs when the

female appliance is in place. During the flow of urine a 5—10 cm water pressure (positive) is present in the portion of the system above the valve. When the flow stops this pressure

- 5 immediately drops to a negative value resulting in a vacuum level of 30—40 cm of water. The upstream hydrophobic filter vent in the valve then allows air to enter the system until equilibrium is reached. In the arrangement described this is
- 10 approximately 8—10 cm of water vacuum. The system remains at this level, thereby ensuring no leakage between the appliance and the vestibular tissue, until the urine again flows freely through the appliance causing a rise of pressure in the
- 15 system to a positive value of 5—10 cm of water and the cycle is repeated. The use of a second filter vent port on the downstream side of the valve permits diffusion of any gaseous pressure build up within the collection bag and thereby
- 20 relieves any deleterious effect such pressures may have on the valve. An excessive pressure build up within the bag could cause the valve to remain in a closed position and thereby prevent introduction of additional fluid into the bag or alternatively, the
- 25 development of a large head or column of liquid on the inlet side of the valve which might result in leakage around the appliance.

These and other objects of the present invention will become clear upon reading the

30 detailed description and upon making reference to the drawings contained herein.

#### Summary of the present invention

In accordance with the objects of the present invention, there is herein disclosed a female

35 urinary appliance adapted to sealingly externally engage the female human form. The female urinary appliance of the present invention can be used to collect urine from a subject in a semi-continuous or even a continuous manner.

- 40 Furthermore, the present invention can be used by the female human subject to collect urine while the subject is an upright or standing position, a generally supine position or a sitting position.
- 45 The appliance seals when gently held in place. The appliance firstly makes a sealing engagement against the mucous membrane surrounding the meatus urinarius and secondly makes a sealing engagement against the vestibule. To make such
- 50 a dual-natured sealing engagement, the appliance has been provided with a pair of raised sealing surfaces. Gentle pressure applied to a backside or underside of the appliance located opposite a urine-receiving cavity causes one of the two raised
- 55 sealing surfaces and a raised portion of the appliance to co-operate to force tissue surrounding the meatus urinarius to protrude markedly into the urine-receiving cavity of the appliance, thereupon directing a stream of urine
- 60 exiting the urethral orifice into such cavity. The sealing engagement of the appliance is additionally enhanced by nature of the general frontal shape and surface geometry of the sealing surfaces, which have been adapted to essentially

- 65 match the angle and body surfaces of the vestibule of the female human form.

More particularly, the appliance sealingly engages the vestibule and isolates the orifice of the urethra from the orifice of the vagina. Bodily

70 engagement with the vestibule comprises a series of sealing engagements between the labia minora, the meatal prominence between the orifice of the vagina and the orifice of the urethra, and certain other tissue located proximate to the

75 clitoris but disposed slightly away from the clitoris in the direction of the orifice of the urethra.

In a second embodiment of the invention, instead of an avoid or egg-shaped external configuration the second embodiment relates to a

80 pair of generally elliptical configured ridges having a gentler slope between opposite ends of the major axis of the device. This has been established through empirical application to a variety of female subjects to establish a semi-

85 universal configuration for adult female human forms.

The second embodiment of the improved appliance is also utilized as part of a system in which the appliance is initially applied by the

90 application of gentle pressure to the backside of the appliance either manually or preferably by use of panties having an aperture centrally disposed in the crotch thereof. When using one preferred embodiment of the improved appliance it has been

95 found desirable to interconnect, between the urine collector and the drainage channel for the improved appliance, anti-reflux valve means. As urine flows from the appliance through the connector tube and valve into the urine collector a

100 vacuum is developed at the sealing surfaces of the appliance which is caused by the Venturi effect of urine flow. The vacuum level achieved is a function of the length of the connector tube, its diameter and the relative height of the appliance

105 in relation to the urine collector and valve. The development of such a vacuum condition for the appliance at the bodily areas of engagement with the female enhance the seal with the vesicular tissues.

110 This vacuum effect can become cumulative during subsequent discharge of urine and may reach a level that can cause discomfort to the wearer. In solution of this problem the valve member can be provided with one or more vent

115 ports utilizing the hydrophobic filter means which provides a vent to permit ambient pressures to reach the inside of the system and to reduce the vacuum level experienced by the user.

In summary, the second embodiment of the

120 improved appliance, according to the present invention, is a one piece external female urine collection device adapted to be positioned within the labial folds of the user, to be in contact with the vestibular tissue around the meatus and to be

125 held gently and stabilized by mechanical means but enhanced by a gentle vacuum condition. The appliance comprises a generally elliptical and open cup-shaped member, and has a generally centrally disposed bore opening so that urine can

flow freely through the member and the bore of the appliance. The upper surface of the appliance includes a generally elliptical and inwardly directed close-looped cusped surface and a substantially continuous curved ridge extending upwardly therefrom. Portions of the appliance upper surface which are disposed away from the cusped surface opposite the curved ridge and the curve ridge define dual upper portions of a cavity within the member. Such dual upper portions form an adjacent pair of sealing surfaces extending substantially continuously around the outer perimeter of the device. The inner surface is disposed farther upwardly, away from the cavity, relative to the outer surface. Depending from a backside of the member and integral therewith, and communicating with the bore opening and the cavity is a stem or cylindrical flange. The configuration of such stem is adapted to prevent interference of fluid flow through the bore opening by forming a thin walled chamber and a lower thick wall portion at the end of the chamber opposite the appliance and adapted to be connected to the tubing leading to the valve. Such heavier section and flexible thin walled chamber are adapted to avoid the kinking problem and prevent interference of fluid flow through the bore opening.

In addition to being generally elliptical in shape, the open cup-shaped member has a gently sloping surface geometry which permits the appliance to be snugly secured to the above described vestibular tissue without excessive pressures and with such snug sealing application to be enhanced by a gentle vacuum condition imposed upon the appliance cavity.

#### Brief description of the drawings

Fig. 1 is a perspective view looking down upon a portion of a pair of sealing surfaces located around the cavity at the urine receiving end of the appliance;

Fig. 2 is a second perspective view of the appliance, again looking down upon the sealing surfaces as in Fig. 1, but with the appliance rotated approximately 180° about a central axis;

Fig. 3 is a top view looking down upon the urine-receiving cavity of the appliance, illustrating the essentially egg-shaped nature of the sealing surfaces;

Fig. 4 is a sectional side view of the female appliance, taken along line 4—4 of Fig. 2, illustrating an anti-kinking feature of a drainage channel which is adapted to permit urine to flow freely out of the cavity, even after the drainage channel is disposed away from the central axis by as much as 90°;

Fig. 4A is a sectional side view of the female appliance similar to Fig. 4 except that the drainage channel is bent and disposed in a position substantially 90° from that shown in Fig. 4 to more clearly illustrate the efficacy of the anti-kinking feature;

Fig. 4B is a sectional end view of the appliance shown in Fig. 4A when rotated 90° along its

drainage channel axis to illustrate the opening available through the anti-kinking feature;

Fig. 5 is a perspective illustration of the appliance functionally connected to a fluid reservoir and used in connection with a preferred form of a commercially available bodily securement and collection device;

Fig. 6 is a perspective illustration of a frontal view of the preferred form of the bodily securing device;

Fig. 7 is a perspective illustration of a rear view of the preferred form of the bodily securing device, as the securing device engages the female human form;

Fig. 8 is an illustration of the external female organs of generation showing regions of frontal engagement of the sealing surfaces of the appliance with the female human form;

Fig. 9 is a vertical median section of the female pelvic region illustrating approximate orientation and bodily engagement of the appliance while the subject is either in an upright, a generally supine, or a sitting position;

Fig. 10 is a perspective view of a preferred embodiment of the improved female urinary appliance, in accordance with the present invention;

Fig. 11 presents a side view of the appliance shown in Fig. 10;

Fig. 12 is a top view of the appliance shown in Fig. 10;

Fig. 13 is a side elevational view in section taken along the line 13—13 in Fig. 12 and showing one means for attaching the collection tubing to the female appliance;

Fig. 14 is a side elevational view in section of the device shown in Fig. 13 and illustrates the anti-kinking feature of the present invention;

Fig. 15 is another modification to the present invention showing the use of an insert molded connector device usable for attaching discharge tubing to the female appliance;

Fig. 16 is a further embodiment of the means for connecting discharge tubing to the female appliance;

Fig. 17 is still another embodiment of further means for connecting the discharge tubing to the female element;

Fig. 18 is a side elevational view in partial section of the system utilizing the female collection appliance of the present invention;

Fig. 19 is a side elevational view of a valve and filter mechanism used in the system shown in Fig. 18;

Fig. 20 is an elevational view in section, taken along line 20—20 of Fig. 19;

Fig. 21 is a plan view of the flapper valve used in the filtered valve shown in Fig. 20;

Fig. 22 is an elevational view of a second form of valve, in partial section, of the type usable in the system shown in Fig. 18; and

Fig. 23 is an exploded side sectional view taken along line 23—23 of the valve shown in Fig. 22.

Throughout the drawings, like reference numerals refer to like parts.

#### Detailed description of the preferred embodiment

5 Turning now to Fig. 1, the appliance 10 is shown in perspective and comprises a receptacle 12 and a hollow stem 14. The receptacle 12 contains a cavity 16. The cavity 16 has an entrance opening 18 which is essentially a  
10 vertical extension of the cavity 16.

The cavity 16 is essentially radially oriented about a central axis 10; and the receptacle 12 has a generally ovoid or egg-shaped external perimeter and a generally elliptical or oval-like  
15 inner cross-section both of which are oriented perpendicularly to the central axis 20.

The opening 18 is provided with two generally elliptical sealing surfaces 22, 24 generally convex in section. Each sealing surface protrudes from the receptacle 12 in a saddle-like fashion along the direction of the central axis 20. Each sealing surface, in side view, is provided with two ridges interposed between two peaks (or summits) and each peak is positioned proximate to a respective  
25 end of the major axis of the receptacle 12.

The first (or inner) substantially continuous sealing surface 22 is provided with a first or front peak 26 which is adapted to sealingly engage with the female human form at a first point just below the clitoris. Such first point is generally located between the clitoris and the orifice of the urethra, and is usually located proximate to the clitoris, but slightly displaced from the clitoris in the direction of the orifice of the urethra. The  
35 inner sealing surface 22 is also provided with a second or rear peak (or "hump") 28 which is adapted to sealingly engage with the female human form at a second point located between the orifice of the urethra and the orifice of the vagina.  
40 The inner sealing surface 22 is provided with a first pair of spaced oppositely disposed side or connecting ridges 30, 32 which are adapted to sealingly engage with the underside or inner surfaces of the two labia minora along an  
45 opposed pair of first elliptical regions.

The second (or outer) sealing surface 24 is positioned essentially along the outer periphery of the first sealing surface 22. The surface contours of the outer sealing surface 24 are blended into the first sealing surface 24 at the first peak 26.  
50 The second sealing surface 24 is also provided with a second pair of ridges 34, 36 which similarly are adapted to sealingly engage with the two labia minora along an opposed pair of second elliptical or oval regions. Except for the blend of surface 24 with peak 26, each respective second elliptical or oval region is displaced slightly away, both radially and axially, from its adjacent first elliptical region, as illustrated in Figs. 1 and 2.  
55

60 The outer sealing surface 24 is provided with another peak 38 which is adapted to sealingly engage with the female human form at a third point located between the second point and the orifice of the vagina.

65 The surface geometry of the receptacle 12 is such that the inner sealing surface 22 generally protrudes out and farther away from the main portion of the receptacle 12 than does the outer sealing surface 24. Such protrusion is in a saddle-like fashion and is along the direction of the central axis 20.

The surface contours of the inner sealing surface 22 and the outer sealing surface 24 are convexly curved in an outward direction, the curvature being positively directed away from the cavity 16. In addition, the inner sealing surface 22 smoothly blends into the cavity 16, thereby providing the opening 18.

The inner sealing surface 22 and the outer sealing surface 24 each has a wall sufficiently thick that the inner sealing surface 22 and the outer sealing surface 24 each maintains its shape and does not deform when the urinary appliance 10 is held in place against the female human form by gentle pressure generally applied along a backside or underside of the receptacle 12 opposite the cavity 16. The inner and outer sealing surfaces 22, 24 of the appliance 10 each permit the appliance 10 to make a sealing  
80 engagement with the tissue surrounding the meatus urinarius. The surface curvature, saddle-like contours and elliptical cross section of the two sealing surfaces of the appliance 22, 24, and more particularly, the raised "hump" or peak 28 of the inner sealing surface 22, cooperate with the outer sealing surface 24 to produce a gentle bulging of meatal (meatus urinarius) prominence into the cavity 16 of the appliance 10, thereby causing the stream of urine to be directed into the receptacle cavity 16.  
90 100

The dual sealing surfaces serve two purposes. First, if a sample of urine is to be used for analysis, it will not be contaminated by vaginal discharge; and second, the normal menstrual cycle can be separately attended to through the ordinary use of commercially available catamenial devices without interfering with waste fluid handling.

Figs. 1, 2 and 3 illustrate the surface geometry of the inner and the outer sealing surfaces 22, 24 of the appliance 10; and Figs. 8 and 9 illustrate how the appliance 10 makes a sealing engagement with the female human form.

The hollow stem 14, shown in Figs. 1, 2 and 4, is radially oriented about the central axis 20 and is integral with a portion of the backside or underside of the receptacle 12 opposite the cavity 16. The hollow stem 14 communicates with the cavity 16 and provides the cavity 16 with an outlet 40. Looking essentially down the central axis 10 and into the cavity 16, the inner diameter of the hollow stem 14 is essentially circular. The hollow stem 14 has a somewhat constant wall thickness, and has an outer diameter which progressively decreases, to a slight degree, moving outwardly from the receptacle 12.  
110 115 120 125

The hollow stem 14 has a sufficient wall thickness and is made of a sufficiently resilient substance that "kinking", which normally would interfere with flow or urine out of the cavity 16,

does not occur since the hollow stem 14 is provided with an "anti-kinking" feature including a hollow transitional portion 42 (which includes outside corner 42a, horizontal flange 42b and inside corner 42c) and a hollow collar 44, to reduce the likelihood of kinking.

A drainage channel (for the cavity 16) is integral with the backside or underside of the receptacle 12 opposite the cavity 16 and includes the hollow stem 14, the hollow transitional portion 42, and the hollow collar 44. As illustrated in Fig. 4, the hollow stem 14 is integral with the hollow transitional portions 42 a, b, and c; and the hollow transitional portions 42 are integral with the hollow collar 44 which is also integral with the backside or underside of the receptacle 12 opposite the cavity 16.

For the purposes of describing the drainage channel, the inner diameter of the hollow stem 14 progressively slightly decreases, moving outwardly and away from the main portion of the receptacle 12, while the hollow stem 14 wall thickness remains substantially constant. As a part of the anti-kinking feature of the drainage channel, the hollow stem 14 has a greater wall thickness than the hollow transitional portions 42a, 42b, and 42c which themselves have a greater wall thickness than the hollow collar 44.

The hollow nature of the stem 14, the transitional portion 42 and the collar 44 permit communication between the cavity 16 and the outlet 40. The relatively thin-walled hollow collar essentially eliminates the detrimental effects caused by kinking when the drainage channel becomes bent during use. As can be seen in Figs. 4a and 4b, the drainage channel can be bent up to 90° away from the central axis 20 and substantially full flow from the outlet 40 is maintained.

The progressively reduced thickness of the various elements moving axially upwardly from stem 14 through transition portion 42 into the hollow collar 44 permits the inward collapse of collar 44 on one side thereof to form at least an elliptical shaped opening, i.e. a somewhat flattened end to stem 14 where it is attached to transition portions 42, that opens into the remaining interior of collar 44. This can be best seen in Figs. 4A and 4B and insures an open drainage channel even when the stem 14 is moved substantially 90° from its normal position when the patient moves from a standing or supine position to a sitting position.

Like the hollow stem 14, the hollow transitional portion 42 and the hollow collar 44 each has an essentially circular cross section. The outer diameter of the hollow collar 44 is significantly greater than the outer diameter of the hollow transitional portion 42, which itself is slightly greater than the outer diameter of the hollow stem 14.

When gentle pressure is applied in a direction generally parallel to the central axis 20 along the backside or underside of the receptacle 12, the inner and the outer sealing surfaces 22 and 24,

and more particularly, the hump 28 co-operate to cause the inner and the outer sealing surfaces 22, 24 to effectively isolate, separately seal off, and provide the cavity 16 of the receptacle 12 with a pair of sealing engagements with the female human form. One sealing engagement is generally made around the orifice of the urethra. These dual sealing surfaces 22, 24 not only ensure a tight seal with minimum pressure, but also stabilize the appliance 10 against up and down or sideways movement.

The appliance 10 is manufactured from a suitable soft rubber, rubber-like or plastic substance.

The appliance 10 can be held in place against the female human form by any one of a variety of commercially available devices designed to bring the appliance into a sealing bodily engagement. For example, the appliance 10 can be held in place with a strap or belt arrangement. The described embodiment, illustrated in Fig. 5, shows just such an arrangement comprising a belt 46, four straps 48, 50, 52 and 54, and a pad 56.

The belt 46 is adapted to fit circumferentially around the waist of the subject and is manufactured from a suitably elastic material so that it will remain substantially in place when drawn downwardly by the action of the straps. The preferred belt is a commercially available variety made from a combination of cloth and elastic. The preferred belt has been provided with a commercially available closure device 47 ("VELCRO") to fit multiple waist sizes.

The four straps 48, 50, 52 and 54 also are made of a suitable elastic material so that the pad 56 is caused to apply gentle pressure to the backside or underside of the receptacle 12 opposite the cavity 16 when the belt-and-strap arrangement is worn by a subject who is in a standing, sitting or otherwise generally supine position. In the preferred embodiment, each strap comprises a cloth portion and an elastic portion. Each cloth portion is attached to the belt 46 and each elastic portion to the pad 56, as illustrated in Figs. 5, 6 and 7. This manner of attachment causes the pad 56 to conform to the backside or underside of the receptacle 12 opposite the cavity 16, thereby effecting the above described sealing engagements. In the preferred embodiment the two lower (or outer) straps 48, 54, are illustrated in Figs. 6 and 7, as passing on either side of the rectum, following the gluteal fold and thereafter being attached to the belt 46. In this embodiment, these lower straps 48, 54 are attached to the belt 46 either at the hipbone or at the anterior superior iliac spine of the pelvis. Also illustrated in Figs. 6 and 7, are top (or inner) straps 50, 52 which have been adjacently attached to the belt 46 at positions proximate to the respective lower straps 48, 54. In the preferred embodiment, in addition to being elastic and therefore stretchable, these inner and outer straps are adjustable in length, as well.

The pad 56 is made of a suitable soft and

pliable material. In the preferred embodiment, the side of the pad which is directed toward the female human form is made of a soft, felt-like material; while the backside of the pad, which is directed away from the female form, is fiber reinforced. The preferred pad is somewhat disc-like in shape and somewhat larger in cross section than the cross section of the backside or underside of the receptacle 12 opposite the cavity 16, so that gentle pressure can be applied generally over the entire backside or underside of the receptacle 12 opposite the cavity 16. The straps 48, 50, 52 and 54 are usually attached to the outer periphery of the pad 56 in a fashion which permits the pads 56 to make substantial surface contact with the backside or underside of the receptacle 12 opposite the cavity 16.

The pad 56 has a hole 58 approximately centrally located therein. In the preferred embodiment, when the appliance 10 is brought into sealing bodily engagement with the female human form, the hollow collar 44 protrudes outwardly through the hole 58 and away from the body of the subject. As it is being used in this preferred embodiment, the appliance 10 is connected by suitable connection means 6 (such as a union) to a piece of tubing 62 having appropriate diameter and suitable resiliency. The piece of tubing 62, in turn, is connected to a fluid reservoir 64, the fluid reservoir 64 having suitable connection means 66 and clamping means 68. During the day the fluid reservoir 64 can be a leg bag, and at night can be a drainage bag. A portion of the piece of tubing 62 is normally taped to the thigh of the subject above the knee.

As the portion of the piece of tubing 62 is taped to the leg, the hollow stem 14 resists kinking at the backside or underside of the receptacle 12 opposite the cavity 16. As the hollow stem 14 is bent away from the central axis 20, first the hollow collar 44, then the hollow transitional portion 42, then lastly the hollow stem 14, deform. The relatively large thin inner diameter of the hollow collar 44 (as contrasted with that of the hollow stem 14) permits significant disposition of the drainage channel from the central axis 20, while maintaining free flow of urine out of the cavity 16. The hollow stem 14 can be bent approximately 90° away from the central axis 20; and urine flowing into the cavity 16 will continue to flow out of the cavity 16 through the outlet 40 into the tubing 62.

The hole 58 in the pad 56 is slightly larger than the hollow collar 44 to allow for such bending or freedom of movement of the drainage channel or the piece of tubing 62 without kinking or binding or either.

In this embodiment, manufacture of the appliance has been made using commercially available injection molding means. Normally, rubber, rubber-like or plastic urinary appliances are made by a dipping process; and it is very difficult to control wall thicknesses. In the present invention, the control of wall thicknesses of the

collar, the hollow transitional portion and the hollow stem can be critically controlled by a commercially available injection moulding process. In the preferred embodiment, the appliance is either made from a suitable thermoplastic rubber polymer or a medical grade elastomer (such as a liquid silicone rubber).

Referring once again to the drawings and to Figs. 10—14, an illustrative preferred second embodiment of the improved appliance will now be discussed.

The appliance 130 is a one-piece external female urine collection device adapted to be positioned within the labial folds of the user (generally along the inner surfaces or undersides thereof) and adapted to be in contact with the vestibular tissue around the meatus defining the urethral opening. The appliance 130 includes a generally elliptical and open cup-shaped member 132 with a tapered upper chamber 134 terminating at its narrow end in a generally centrally disposed bore opening 136 so that urine can flow through the member 132 and the appliance 130. The upper surface geometry of the appliance 132 includes a generally elliptical and inwardly-directed close-looped cusped surface 138 and a substantially continuously curved ridge 140 extending upwardly therefrom. Portions of the appliance 130 upper surface which are disposed away from the cusped surface 138 opposite the curved ridge 140 are designated as surface 142, define and form an adjacent pair of sealing surfaces 140, 142. The inner surface 140 is disposed farther upwardly, away from the cavity 134, relative to the outer surface 142.

Depending substantially perpendicular from a backside (referred to generally by the reference numeral 144; see Figs. 11 and 13) of the member 132 and integral therewith is a relatively thin-walled cylindrical flange or tubular member 146 which communicates with the bore opening 136 and provides the cavity 134 with a drainage channel. The flange 146 is oriented about the axis 148 (see Fig. 13). Further details on the cylindrical flange or tube 146 will be set forth hereinafter.

The sealing surfaces 140, 142 and member 132 are oriented about an axis 150 which is substantially parallel to the axis 148 and which is displaced therefrom by the distance D (Fig. 13). As viewed from above the appliance 130 (Fig. 12), the projections of the sealing surfaces 140, 142 are generally elliptical. The appliance 130 is seen to have a major axis "A" which passes through axes 148 and 150 and a minor axis "B" which is oriented laterally in relation to the axis 148 but perpendicular in relation to the major axis "A" (Fig. 12). Both of these axes "A" and "B" form a plane which is substantially perpendicular to the axis 148. Moreover, referring to Fig. 11, it will be seen that the lateral projection of the appliance 130 is also generally elliptical along a second plane which either contains or is substantially parallel to the axis 148 with a semi-minor axis "C" oriented vertically, as is the axis 148.

Generally in the plane formed by the axes "A", "B" (Fig. 12), or in a plane (not shown) generally parallel thereto which is perpendicularly disposed in relation to the axis 150, is an origin (arbitrarily presented in Fig. 12) for a first radius of curvature R1, which generally describes the elliptical external edge boundary of the appliance 130. A second radius of curvature R2, having a second origin, located in position generally as described above for the first origin, generally describes the location of the cusped surface 138 separating the adjacent sealing surfaces 140, 142. Within the plane formed by the axes "A", "C" (Fig. 11) and from a point or origin, located on the axis 150, exterior to the appliance 130 (Fig. 13) a third radius of curvature R3 describes the gently sloping surface geometry (of the appliance 130) at the entrance to the cavity 134 where the appliance 130 generally makes engagement with the vestibule and labial folds of the female. As best seen in Fig. 13, the end surfaces of the appliance 130 are defined by points of origin falling on the axis "A" wherein the radius R5 defines the end external geometry of the appliance 130 while the radius R4 defines the cusped surface 138.

Vacuum sealing of the improved appliance 130 with the female is generally achievable when the following values are maintained. Referring now to Figs. 11 and 12, the length 160 along axis "A" ranges from about 1.5 inches to about 1.88 inches (about 4.01 to about 4.78 cm). Length 160 is preferably about 1.73 inches (about 4.39 cm). The width 162 taken along axis "B" ranges from about 1.03 inches to about 1.23 inches (about 2.62 to about 3.12 cm). The width 162 is preferably about 1.13 inches (about 2.87 cm). The nominal projection height "C" ranges from about 0.37 inches to about 0.47 inches (about 0.94 to about 1.19 cm). "C" is preferably about 0.42 inches (about 1.07 cm). The offset relationship defined by the distance "D" ranges from about 0.070 inches to about 0.086 inches (about 0.178 to about 0.218 cm). "D" is preferably about 0.078 inches (about 0.198 cm). R1 ranges from about 1.50 inches to about 1.80 inches (about 3.81 to about 4.57 cm). R1 is preferably about 1.65 inches (about 4.19 cm). R2 ranges from about 0.975 inches to about 1.175 inches (about 2.48 to about 2.98 cm). R2 is preferably about 1.075 inches (about 2.73 cm). R3 ranges from about 0.915 inches to about 1.115 inches (about 2.32 to about 2.83 cm). R3 is preferably about 1.015 inches (about 2.58 cm). R4 ranges from about 0.393 to about 0.48 inches (about 1.00 to 1.22 cm). R4 is preferably about 0.4375 inches (about 1.11 cm). R5 ranges from about 0.450 inches to about 0.550 inches (about 1.143 to about 1.397 cm). R5 is preferably about 0.500 inches (about 1.27 cm). R6 ranges from about 1.485 inches to about 1.815 inches (about 3.77 to about 4.61 cm). R6 is preferably 1.650 inches (about 4.191 cm).

The adjacent sealing surfaces 140, 142 which are continuous and provide dual adjacent sealing

surfaces around the entire periphery of the appliance 130, permit the appliance 130 to sealingly and continuously make contact with the female by engaging with the inner portions of the labial folds and the remainder of the abovementioned vestibular tissue.

Referring now more particularly to the cylindrical tube-like flange 146, as best seen in Figs. 13 and 14, the flange 146 is a thin walled member having a wall thickness in the range of about .025 to about .035 inches and preferably about .031 inches with the length of the thin walled portion, as measured from the backside 144 of the member 132, being only slightly greater than the inner diameter of the flange 146. A thick wall extension 152 includes a central aperture 154 and a counterbore lower bore 156 capable of accepting a length of tubing 158 having an internal bore substantially equal to the bore of the opening 154 whereby free unrestricted flow into the tubing is permitted. The tubing 158 is fixed within the counterbore 156 by suitable means known in the art such as adhesive or heat sealing. As can be best seen in Fig. 14 deflection of the flange 146 results in a slight closure to the internal diameter thereof by a flexing of one side and stretching of the other side without a closing off of the bore and thereby permitting a free passage unimpeded of the urine through the inside of the flange 146, the thickened portion 152 and the tubing 158 to a suitable collector. This anti-kink feature can be readily accommodated and integrally fabricated within a female urine collection device of the type disclosed hereinabove.

Referring now to Figs. 15—17 additional embodiments of the connecting means are shown and wherein similar parts are designated by similar numerals with the additions of the suffixes a, b and c. In Fig. 15 the flexible flange 146a includes a thickened portion 152a having a centrally disposed bore 154a and a tubing connector 170 with an enlarged flange 172 insert molded within the thickened portion 152a. The tubing connector 170 includes at its free exposed end a plurality of stepped shoulders 174, of the type well known in the art, for expanding and providing a sealed acceptance and passage to the interior of tubing 158a which has been expanded thereover. The connector 170 has a central bore not shown, substantially equal to the diameter of the bore 154a to provide unimpeded through flow of urine from the female appliance, not shown.

A second embodiment of connecting means discloses the thin wall flange 146b, in fragmentary section, and in which the terminal ends 176, initially co-axial therewith, are bent inwardly to form an inwardly directed flange 178 secured to the tubing 158b by adhesive or heat sealing means, shown in Fig. 16.

Fig. 17 is still another embodiment in which the thin wall flange 146c, shown in fragmentary section, is provided with an inwardly directed flange 180 and a downwardly directed cylindrical flange 182. The inwardly directed flange 180 has

a central bore adapted to accept tubing 158c while the downwardly directed flange 182 forms a chamber or pocket between itself and the tubing 158c to accept a sealing ring 184 of either adhesive or other known O-ring types of sealing and retaining mechanisms.

The anti-kink feature in each of the last three embodiments shown in Figs. 15, 16 and 17 all function in the same fashion as that shown in Fig. 14, namely, a thin wall flange terminated by a thick wall rigid portion which will orient the bending and stretching in the thin wall portion 146a, b and c without kinking or total shut off of the urine flow therethrough.

Referring now to Figs. 18—23 and particularly Fig. 18 wherein the system of the present invention is generally disclosed. The appliance 130 is preferably connected to a urine collection vessel or urine collector bag 190 (Fig. 18). The urine collector 190 is usually a sealed and initially flat plastic sack or bag of the type well known in the art. The appliance 130 can be initially secured to desired vestibular tissue of the female, as set forth hereinabove, by imposing a gentle securing and compression means such as a pair of panties 192 (only the crotch being shown in section) which have a centrally disposed aperture to accept the downwardly extending portions 146 and 152. Preferably a minipad 194 having an adhesive layer 196 for securement to the panties 194 serves to stabilize the collector 130 and to maintain it in the predetermined desired location. This is supplemented by imposing a gentle vacuum condition upon the cavity 134 of the appliance 130. One known method of imposing such a vacuum condition upon the cavity 134 is by maintaining a preselected head of liquid (such as urine) beneath the appliance 130. To accomplish this the anti-reflux valve of the present invention is preferably interconnected between the appliance 130 and the collector 190 to control the head of urine and vacuum. The novel valve 200 includes a valve structure 202 which defines a valve inlet 204 and a valve outlet 206 and encloses a flapper-type valve 208. One preferred form of flapper valve 208 includes a flap 210 which is integral through a neck 212 with a circumferential circular collar 214, see Figs. 20 and 21. As best seen in Fig. 20, the valve inlet 104 includes an annular axially extending rounded edge flange 220 serving as a seat against which the flap 210 can position itself in a normally closed relation while outboard thereof there is a second flange 222 axially directed and terminating in the same plane as flange 220 and diametrically outwardly thereof a shoulder 224. Valve outlet 206 includes a counterbore forming a shoulder 226 and an axially extending flange 228. The valve inlet 204 and valve outlet 206 with their co-axial arrangement cause the flange 222 and shoulder 226 to grip the collar 214 in a tight sealed relationship. Such sealing can be accomplished by either bonding with a commercially available adhesive or alternatively by heat sealing the two plastic portions together.

By maintaining the axial extent of flanges 222 and 228, to accommodate the thickness of the flapper valve 208 a normally closed positive seating occurs between the flap 210 and the axially directed flange 220 serving as the seat for flap 210. As urine flows downwardly a predetermined head of urine is established within the tube 158 and acts against the flap 210 and causes it, upon establishment of such head, to bias to an open position in a known manner.

The flap 210 engages, substantially covers, and seals against the seat formed by flange 220 and thereby maintains an initial head or column of urine (or other liquid) in the tubular portion 230 of valve inlet 204 (liquid not shown). The flapper type valve 208 is made of a commercially available suitably resilient substance which permits the initial head or column of liquid to assume a predetermined value. The preferred flapper-type valve is made of an approximately 0.005 inch (approximately 0.13 mm) thick polyester film. The neck 212 and collar 214 cooperate to bias the flap 210 against the seat 230 thereby preventing such liquid from flowing out of the tube 230 via the valve outlet 206.

As the column of liquid increases in height, the weight of liquid in the tube 230 eventually increases to the point where the flap 210 is urged away from the seat 220. Whereupon the height of the column of liquid quickly decreases in the tube 230 and tube 158 as the liquid flows past the flap 210. Most of this liquid usually immediately flows out the valve outlet 206, preferably filling the collector 190 connected thereto. The height of liquid in the tube 230 is quickly reduced to a point where the flap 210 can again support the weight of liquid in the tube 230. Whereupon, the flap 210 again moves upwardly against the seat 220, through the biasing action of neck 212, and seals the seat 220.

It has been noted however, that the passage of urine through the appliance 130 and the tube 158 and valve 200 develops through a Venturi-like action an initial vacuum condition which is imposed by the appliance 130 to the body of the female, and as the female discharges additional urine into the cavity 134 of the improved appliance 130, a marked feeling of increasing discomfort is felt (over time) at the vestibular tissue to which the improved appliance 130 has been applied. It has been observed, indirectly, that as urine is discharged into the cavity 134 of the improved appliance 130, such urine entrains some of the air and certain other gases initially present in the cavity 134. Such entrainment depletes the cavity 134 of an initial amount or quantity of air or other gas and serves to increase, over a period of time, the vacuum sensation.

Between the flap 210 and the improved appliance 130, the inlet portion 204 of the valve structure 200 includes a first vent 240 through which air and certain other gas is permitted to pass so that an initial vacuum condition, imposed upon the cavity 134 of the improved appliance 130, can be maintained.



Such a vent includes a hydrophobic filter or membrane 242 covering the vent 240 and permitting the ingress or egress of gases but, because of its hydrophobic nature, prevents the passage of liquids such as urine. Within the tubular portion 230 the height of liquid is generally well above the vent 240 and it is the hydrophobic filter 242 which prevents liquid from leaking out of the tubular portion 230. The filter membrane 242 has a pore size such that most gas is permitted to diffuse therethrough, but such that urine or other liquids are not permitted to noticeably or appreciably diffuse therethrough.

When the pore size ranges from about 3 microns to about 15 microns (a preferred pore size range), no diffusion of urine has been noted.

The illustrated embodiment of the system including the improved appliance 130 with its outlet flange 146, 152 is connected to a piece of hollow and flexible plastic tubing 158, of suitable length, is usually used to connect the appliance 130 to the valve 200 in accordance with the present invention. In most applications a length of about 8 inches for the tubing 158 is preferred. During the flow of urine a 5—10 cm of water pressure (positive) is present in the portion of the system above the valve. When the discharge or urine flow stops, this pressure immediately drops to a negative value resulting in a vacuum level of 30—40 cm of water. The upstream hydrophobic filter vent 240 in the valve 200 then allows air to enter the system until a semi-equilibrium condition is reached. In the arrangement described this is approximately 8—10 cm of water vacuum. The system remains at this level, insuring tight engagement of the appliance 130 with the vestibular tissue, until urine again flows causing a rise of pressure in the system to a positive value of 5—10 cm of water and the cycle is repeated. The equilibrium vacuum level is determined in part by the length of tube and vertical distance the appliance is located above the valve. The top connector in the valve (above the upstream vent) generally has an inside diameter of from about 0.175 inches to about .280 inches with a preferred optimum inside diameter of approximately .200 inches to achieve the pressure/vacuum sequence described above.

It should be noted, that as the female discharges urine into the cavity 134 of the improved appliance 130 and as urine flows down the tube 158 and through the valve 200, it has been observed that minute bubbles can be seen in the column of urine. Such bubbles first appear at the liquid side of the semi-permeable membrane 242 have been seen to pass through the vent opening 240 and inwardly in the urine in the tubular portion 230 of the valve 200. Without the vent opening 240 being present on the tubular portion 230 no such bubbles were observed.

Furthermore, it has been observed that the height of the column of liquid in the valve 200 and the tubing 158, in addition to being caused by the biasing action of the neck 212 of the

flapper-type valve 208, is a surface tension phenomenon of the particular liquid. For example, when the tubing 154 used is specifically a commercially available extruded latex having a nominal internal diameter (I.D.) of 5/16 inches (nominally about .313 inches or about .794 cm), the height of female human urine in the valve 200 and the tubing 158 was observed to extend generally about 3 to about 4 inches above the vent inlet 240. Such a particular type of commercially available tubing is held to an I.D. tolerance of 1/64 inches (about 0.016 inches or about 0.40 cm). Yet for a nominal tubing I.D. of 3/8 inches (nominally about .375 inches or about .953 cm), it was observed that within such tubing 158 and in the tubular portion 230 of the valve 200 above the vent inlet 240 no such height or column of urine could be maintained. The column of urine in the tubing 158 extended upwardly from the flapper-type valve 208 only generally up to the vent opening 240. Furthermore, for a nominal tubing I.D. of 1/4 inches (nominally about .250 inches or about .635 cm), it was noted that the bubbles (observed in the urine) could not move upwardly in the tubular portion 230 or the valve 200. The nominal 5/16 tubing I.D. experiment was repeated and a substantial amount of commercially available soap solution was added to the column of urine; and the height of urine in the tube 230 and tubing 158 was observed to be markedly less than above noted. For the tubing 158, the preferred nominal I.D. is 5/16 inches. The preferred I.D. at the inlet end portion 204 of the valve 200 is about .200 inches (about .508 cm).

The tubing 158 is preferably substantially translucent while the valve 200 is preferably made of a suitable and clear plastic, and is preferably transparent.

A second suitable length of flexible plastic tubing 198 connects the outlet end portion 206 of the valve 200 to a suitable inlet connection 188 on the urine collector 190. As urine flows downwardly through the outlet valve portion 206 of the valve 200 and fills the collector 190, entrained air and other gas eventually de-entrains, begins to accumulate in the collector 190 and eventually is displaced out of the collector 190 and up the outlet tube 198 where it can interfere with the operation of the flapper-type valve 208.

Accordingly, the outlet portion 206 of the valve 200 preferably includes a second vent opening 244 to permit gas in the outlet tube 198 to pass through the wall of the valve structure 200. This valve vent opening 244 also includes and is covered by a hydrophobic filter membrane 246 which forms a liquid seal thereat. The second membrane 244 is preferably of the same substance and has the same pore dimension as the first membrane 242. It should be noted that both of these membranes can be either insert molded during the fabrication of the inlet portion 204 and the outlet portion 206 of valve 200 or alternatively can be formed as part of a closure cap (not shown) which would be inserted into the

valve ports 240 and 244. It will be appreciated that the downstream hydrophobic filter vent 244 allows air to escape from the collector/leg bag 190 thus permitting a higher fluid level before a back pressure is developed that will impair the proper operation of the system, i.e. entrained air serving to act against the flap 210 to cause it to remain in a closed position resulting in an undesirable head of liquid within the tubing 158 and possible leakage of liquid from the collector unit 130.

While not shown, it has been found that a valve having a single downstream vented port, i.e. vent port 244 with a hydrophobic filter membrane 246 will work adequately to de-entrain air and other gases from the bag and because of the impositive nature of flapper valve 208 will permit sufficient ambient air to enter the system to partially relieve the vacuum condition where the appliance 130 engages the vestibular and labial tissue. Such an embodiment would be identical to that previously disclosed with valve 200 but with the elimination of the upper vent port 240 and its associated hydrophobic filter 242.

The first embodiment of valve and filter (shown in Figs. 19—21) described hereinabove is but one example of an in line valve and filter which can be used. A second embodiment of such a filtered valve can be seen in Figs. 22 and 23. Where the first valve member, namely inlet portion 204 and outlet portion 206 can be molded in a simple blank mold with minimal side action for ports 240 and 244, the second embodiment of Figs. 22 and 23 requires slightly greater tooling expense due to the multiplicity of parts involved. This embodiment of the valve 300 includes a main body 302 having an inlet end 304 suitably shaped to engage the interior of the tubing 158 and an exit opening 306 entering into a biased or canted seat 308. A flapper valve 310 of a design substantially identical to the prior described valve 208 includes a flap 312 engaging the seat 308 and covering the opening 306, a hinge 314 and an encircling body 316. A side opening 320 forming a chamber in the body 302 which includes the seat 308 is closed by a cover member 322 having flange means 324 for engaging the peripheral body portion 316 of the valve 310 to maintain it in tight engagement with the seat 308 but allowing freedom of movement of the flap 312 to open and provide venting through the opening 306. The main body includes an outlet opening 330 adapted to be engagable with the discharge tube 198 that connects with the collector 190.

In this embodiment there is a vent port 332 upstream of the valve 310 and includes an apertured cap 334 capable of accepting a hydrophobic filter 336 which serves the same function as the filters in the previous embodiment. Similarly a downstream vented port 340 is covered by a ported cap 342 which carries a similar hydrophobic filter membrane 344. The function operation of this valve is substantially

equivalent to the first embodiment when used in the system shown in Fig. 18.

It can be appreciated that the flapper-type valves 200 and 300 are but two embodiments of valves adapted to permit liquid to flow in only one direction as required by the present invention. Variations in modifications of flapper valves of this type are generally well known in the art, however, the use of such a valve having a vented port with a hydrophobic filter therein in the environment shown herein is not known to exist in the prior art. A system of the type disclosed provides a gentle mechanical means for initially engaging the vestibular mucosa of the female anatomy and after first discharge of urine ensures continued seal with such vestibular and labial tissues by the maintenance of the vacuum condition. The deleterious effects of the vacuum are generally overcome by the hydrophobic filtered vent ports which reduce the discomfort to the patient but insure an adequate vacuum condition for sealing purposes. The system is economical to fabricate and is reusable through the observance of general cleanliness and known techniques. The female collection device can be injection molded of Kraton® material manufactured by Shell Oil Company; polyethylene; as well as other injection moldable soft rubber-like materials which are comfortable to the female form. The valve elements can be injection molded of suitable plastic materials of a wide variety known to the marketplace and inert to urine.

While specific sizes have been set forth for a collection device that is usable with the "normal adult human female" it should be recognized that narrower units can be used with petite females and that devices which bear the same general proportions but which have a small length and width than the sizes set forth are being developed for use with immature females, i.e. teenagers who suffer incontinence.

What has been illustrated and described herein is a novel system and an improved female urinary appliance. While the valve and the appliance of the present invention have been illustrated and described with reference to several preferred embodiments, the present invention is not committed thereto. On the contrary, alternatives, changes or modifications may become apparent to those skilled in the art upon reading the foregoing descriptions. Accordingly, such alternatives, changes and modifications are to be considered as forming a part of the present invention insofar as they fall within the spirit and scope of the appended claims.

#### Claims

1. A one piece external female urine collection device adapted to be positioned within the labial folds of the user and in contact with the vestibular tissue around the meatus defining the urethral opening, said device comprising a generally avoid and open cup-shaped member having a cavity and a generally centrally disposed bore opening through said member, the upper periphery of said

member having a generally convexly curved exterior surface and a substantially continuously curved ridge extending upwardly therefrom defining the upper portions of said cavity within  
 5 said member, said upper periphery and ridge generally defining a generally adjacent pair of sealing surfaces, an inner one of said adjacent surfaces generally disposed farther upwardly relative to an outer one of said adjacent surfaces,  
 10 for sealingly and continuously contacting and engaging with the labial folds and said vesibular tissue.

2. The urine collection device of claim 1 including a drainage channel integral with said  
 15 member at a backside thereof, extending therefrom and communicating with said bore opening; and means for preventing said drainage channel from kinking.

3. A one piece, soft and pliable appliance  
 20 adapted to sealingly engage with the female human form at vestibular surface tissue generally along the labia minora, a portion of said tissue which is proximate to the clitoris and another portion of said tissue which is proximate to the  
 25 orifice of the urethra and displaced toward the orifice of the vagina, for receiving urinary discharge from a human subject comprising: an open mouthed receptacle having a mouth defining a saddle for engaging with the female of said  
 30 vestibular tissue, said saddle having at least two generally adjacent surfaces of generally outwardly convex curvature, an inner one of said adjacent surfaces generally disposed slightly farther upwardly relative to an outer one of said adjacent  
 35 surfaces, for making sealing engagement with said female along said vestibular tissue, the receptacle including an outlet to permit the discharge to drain therefrom, and means for preventing said outlet from closing and interfering with the  
 40 drainage therefrom.

4. A one piece, soft and pliable appliance adapted to sealingly engage with the female human form at vestibular surface tissue generally  
 45 along underfolds of the labia minora, a portion of said tissue which is proximate to the clitoris and another portion of said tissue which is proximate to the orifice of the urethra and displaced toward the orifice of the vagina, for receiving urinary  
 50 open-mouthed and generally oval receptacle having a mouth defining a saddle for engaging with the female at said vestibular tissue, said saddle defining two generally adjacent surfaces generally disposed slightly farther upwardly  
 55 relative to an outer one of said adjacent surfaces, for making sealing engagement with said female along at least two generally different surface contour portions of said vestibular tissue, the receptacle including a tubular member integral  
 60 therewith and having an outlet adapted to permit the discharge to naturally drain therefrom; and means for preventing said tubular member from kinking and interfering with the natural drainage therefrom.

65 5. A device of the type claimed in claim 2 or

claim 3 or claim 4 wherein said drainage channel outlet includes a chamber, a transition portion and a hollow connecting stem all communicating with said cavity and collectively forming means  
 70 for preventing kinking.

6. A device of the type claimed in claim 5 wherein said chamber has a greater diameter than said transition portion which has a greater diameter than the stem.

7. A device of the type claimed in claim 6 wherein the wall thickness of said chamber, said transition portion and said stem are inversely proportional to their diameters, said chamber wall being thinner than said transition portion which is  
 80 thinner than said stem, whereby, angular movement of said stem up to 90° from its normal disposition causes a partial inversion of said chamber wall and said transition portion but retains an open bore in said stem communicating  
 85 with said chamber and said cavity.

8. A urinary appliance adapted to externally sealingly engage a female human form comprising a receptacle having an opening and containing a cavity, said cavity being radially  
 90 oriented about a central axis, said receptacle having a substantially elliptical cross section oriented perpendicularly to said central axis, said opening having two sealing surfaces, each sealing surface protruding away from said cavity in a  
 95 saddle-like fashion, each sealing surface having two ridges interposed between two peaks, each peak being positioned proximate to a respective end of the major axis of said receptacle, the first sealing surface having a first peak adapted to  
 100 sealingly engage with the female human form at a first point, said first point being located between the clitoris and the orifice of the urethra and being proximate to the clitoris but slightly displaced from the clitoris in the direction of the orifice of  
 105 the urethra, said first sealing surface having a second peak adapted to sealingly engage with the female human form at a second point located between the orifice of the urethra and the orifice of the vagina, said first sealing surface having a  
 110 first pair of ridges adapted to sealingly engage with the two labia minora along an opposed pair of first elliptical regions, each respective first elliptical region being located proximate to one of the two labia minora, the second sealing surface  
 115 being positioned substantially along the outer periphery of said first sealing surface and being blended into said first sealing surface at said first peak, said second sealing surface having a second pair of ridges adapted to sealingly engage with  
 120 the two labia minora along an opposed pair of second elliptical regions, each respective second elliptical region being disposed slightly away from an adjacent first elliptical region and from said central axis, said second sealing surface having a  
 125 third peak adapted to sealingly engage with the female human form at third point located between said second point and the orifice of the vagina, said first sealing surface protruding farther away from said cavity than said second sealing  
 130 surface, said first sealing surface and said second

sealing surface being convexly curved and the curvature being directed outwardly and away from said cavity, said first sealing surface and said second sealing surface each having a wall sufficiently thick that said first sealing surface and said second sealing surface each maintains its respective shape and does not deform when said urinary appliance is held against the female human form by gentle pressure applied substantially along an underside of said receptacle opposite said cavity; whereupon, when gentle pressure is applied along said underside of said receptacle opposite said cavity, said first and said second sealing surfaces co-operate to effectively isolate the vestibule from the orifice of the vagina, separately seal off the meatus urinarius, and provide said cavity of said receptacle with a pair of sealing engagements with the female form firstly around the vestibule of the female human form and secondly around the meatus urinarius of the female human form.

9. A urinary appliance adapted to externally sealingly engage a female human form comprising (a) a receptacle having an opening and containing a cavity, said cavity being radially oriented about a central axis, said receptacle having substantially elliptical cross section oriented perpendicularly to said central axis, said opening having two sealing surfaces, each sealing surface protruding away from said cavity in a saddle-like fashion, each sealing surface having two ridges interposed between two peaks, each peak being positioned proximate to a respective end of the major axis of said receptacle, the first sealing surface having a first peak adapted to sealingly engage with the female human form at a first point, said first point being located between the clitoris and the orifice of the urethra and being proximate to the clitoris but slightly displaced from the clitoris in the direction of the orifice of the urethra, said first sealing surface having a second peak adapted to sealingly engage with the female human form at a second point located between the orifice of the urethra and the orifice of the vagina, said first sealing surface having a pair of ridges adapted to sealingly engage with two labia minora along an opposed pair of first elliptical regions, each respective first elliptical region being located proximate to one of the two labia minora, the second sealing surface being positioned substantially along the outer periphery of said first sealing surface and being blended into said first sealing surface at said first peak, said second sealing surface having a second pair of ridges adapted to sealingly engage with the two labia minora along an opposed pair of second elliptical regions, each respective second elliptical region being disposed slightly away from an adjacent first elliptical region and from said central axis, said second sealing surface having a third peak adapted to sealingly engage with the female human form at a third peak adapted to sealingly engage with the female human form at a third point located between said second point and the orifice of the vagina, said first sealing surface

protruding farther away from said cavity than said second sealing surface, said first sealing surface and said second sealing surface being convexly curved and the curvature being directed outwardly and away from said cavity, said first sealing surface and said second sealing surface each having a wall sufficiently thick that said first sealing surface and said second sealing surface each maintains its respective shape and does not deform when said urinary appliance is held against the female human form by gentle pressure applied substantially along an underside of said receptacle opposite said cavity; and (b) a hollow stem being integral with said underside of said receptacle opposite said cavity, said hollow stem communicating with said cavity and providing said cavity with an outlet; whereupon, when gentle pressure is applied along said underside of said receptacle opposite said cavity, said first and said second sealing surfaces cooperate to effectively isolate the vestibule from the orifice of the vagina, separately seal off the meatus urinarius; and provide said cavity of said receptacle with a pair of sealing engagements with the female human form firstly around the vestibule of the female human form and secondly around the meatus urinarius of the female human form.

10. The urinary appliance of claim 9 wherein said hollow stem is radially oriented about said central axis.

11. The urinary appliance of claim 9 or claim 10 wherein said hollow stem has a circular cross section and an inner diameter which recedes outwardly and away from said underside of said receptacle opposite said cavity.

12. The urinary appliance of claim 11 wherein said hollow stem includes a hollow transitional portion being integral therewith, said hollow transitional portion also being integral with a hollow collar, said hollow collar being integral with said underside of said receptacle opposite said cavity.

13. The urinary appliance of claim 12 wherein said hollow transitional portion and said hollow collar are each radially oriented about said central axis.

14. The urinary appliance of claim 12 or claim 13 wherein said hollow transitional portion and said hollow collar each has a circular cross section, the inner diameter of said hollow collar being greater than the inner diameter of said hollow transitional portion, said inner diameter of said hollow transitional portion being greater than said inner diameter of said hollow stem, said hollow stem having a greater wall thickness than said hollow transitional portion, said hollow transitional portion having a greater wall thickness than said hollow collar.

15. In combination with (a) a pad having a front side which is adapted to be directed toward the female human form, said pad being made of a soft and pliable substance, said pad having attached to the outer edge periphery a plurality of stretchable straps, each stretchable strap having a

first end which is attached to said outer edge  
periphery of said pad and having a second end  
which is attached to a belt, said belt being  
adapted to fit around the waist of a female human  
subject, said belt and each strap individually  
having a length sufficient to cause said front side  
of said pad to apply gentle pressure to an area  
proximate to the vestibule of the female human  
form when said belt is worn in a normal fashion  
around the waist; (b) a urinary appliance adapted  
to externally sealingly engage the female human  
form comprising a receptacle having an opening  
and containing a cavity, said cavity being radially  
oriented about a central axis, said receptacle  
having a substantially elliptical cross section  
oriented perpendicularly to said central axis, said  
opening having two sealing surfaces, each sealing  
surface protruding away from said cavity in a  
saddle-like fashion, each sealing surface having  
two ridges interposed between two peaks, each  
peak being positioned proximate to a respective  
end of the major axis of said receptacle, the first  
sealing surface having a first peak adapted to  
sealingly engage with the female human form at a  
first point, said first point being located between  
the clitoris and the orifice of the urethra and being  
proximate to the clitoris but slightly displaced  
from the clitoris in the direction of the orifice  
of the urethra, said first sealing surface  
having a second peak adapted to sealingly engage  
with the female human form at a second  
point located between the orifice of the urethra  
and the orifice of the vagina, said first sealing  
surface having a first pair of ridges adapted to  
sealingly engage with the two labia minora along  
an opposed pair of first elliptical regions, each  
respective first elliptical region being located  
proximate to one of the two labia minora, the  
second sealing surface being positioned  
substantially along the outer periphery of said first  
sealing surface and being blended into said first  
sealing surface at said first peak, said second  
sealing surface having a second pair of ridges  
adapted to sealingly engage with the two labia  
minora along an opposed pair of second elliptical  
regions, each respective second elliptical region  
being disposed slightly away from an adjacent  
first elliptical region and from said central axis,  
said second sealing surface having a third peak  
adapted to sealingly engage with the female  
human form at a third point located between said  
second point and the orifice of the vagina, said  
first sealing surface protruding farther away from  
said cavity than said second sealing surface, said  
first sealing surface and said second sealing  
surface being convexly curved and the curvature  
being directed outwardly and away from said  
cavity, said first sealing surface and said second  
sealing surface each having a wall sufficiently  
thick that said first sealing surface and said  
second sealing surface each maintains its  
respective shape and does not deform when said  
front side of said pad holds said urinary appliance  
in place against the female human form when  
gentle pressure is applied substantially along an

underside of said receptacle opposite said cavity;  
whereupon, when gentle pressure is applied by  
said pad against said underside of said receptacle  
opposite said cavity, said first and said second  
sealing surfaces co-operate to effectively isolate  
the vestibule from the orifice of the vagina,  
separately seal off the meatus urinarius, and  
provide said cavity of said receptacle with a pair  
of sealing engagements with the female human  
form firstly around the vestibule of the female  
human form and secondly around the meatus  
urinarius of the female human form, thereby  
permitting urine to freely flow from the urinary  
bladder into said cavity without leakage of urine  
from said receptacle.

16. In combination with (a) a pad having a  
front side which is adapted to be directed toward  
the female human form, said pad being made of  
soft and pliable substance, said pad having a hole  
centrally located, therein, said pad having  
attached to the outer edge periphery a plurality of  
stretchable straps, each stretchable strap having a  
first end which is attached to said outer edge  
periphery of said pad and having a second end  
which is attached to a belt, said belt being  
adapted to fit around the waist of a female human  
subject, said belt and each strap individually  
having a length sufficient to cause said front side  
of said pad to apply gentle pressure to an area  
proximate to the vestibule of the female human  
form when belt is worn in a normal fashion  
around the waist, and (b) a fluid reservoir adapted  
to receive and contain urine from the female  
human subject, said fluid reservoir having  
connection means to functionally connect said  
fluid reservoir to a first end of a tube; (c) a urinary  
appliance adapted to externally sealingly engage  
the female human form comprising (1) a  
receptacle having an opening and containing a  
cavity, said cavity being radially oriented about a  
central axis, said receptacle having a substantially  
elliptical cross section oriented perpendicularly to  
said central axis, said opening having two sealing  
surfaces each sealing surface protruding away  
from said cavity in a saddle-like fashion, each  
sealing surface having two ridges interposed  
between two peaks, each peak being positioned  
proximate to a respective end of the major axis of  
said receptacle, the first sealing surface having a  
first peak adapted to sealingly engage with the  
female human form at a first point, said first point  
being located between the clitoris and the orifice  
of the urethra and being proximate to the clitoris  
but slightly displaced from the clitoris in the  
direction of the orifice of the urethra, said first  
sealing surface having a second peak adapted to  
sealingly engage with the female human form at a  
second point located between the orifice of the  
urethra and the orifice of the vagina, said first  
sealing surface having a first pair of ridges  
adapted to sealingly engage with the two labia  
minora along an opposed pair of first elliptical  
regions, each respective first elliptical region  
being located proximate to one of the two labia  
minora, the second sealing surface being

positioned substantially along the outer periphery of said first sealing surface and being blended into said first sealing surface at said first peak, said second sealing surface having a second pair of ridges adapted to sealingly engage with the two labia minora along an opposed pair of second elliptical regions, each respective second elliptical region being disposed slightly away from an adjacent first elliptical region and from said central axis, said second sealing surface having a third peak adapted to sealingly engage with the female human form at a third point located between said second point and the orifice of the vagina, said first sealing surface protruding farther away from said cavity than said second sealing surface, said first sealing surface being convexly curved and the curvature being directed outwardly and away from said cavity, said first sealing surface and said second sealing surface each having a wall sufficiently thick that said first sealing surface and said second sealing surface each maintains its respective shape and does not deform when said front side of said pad holds said urinary appliance in place against the female human form when gentle pressure is applied substantially along an underside of said receptacle opposite said cavity; and (2) a hollow stem being integral with said underside of said receptacle opposite said cavity, said hollow stem communicating with said cavity and providing said cavity with an outlet, said outlet being functionally connected to a second end of said tube; whereupon when gentle pressure is applied by said pad against said underside of said receptacle opposite said cavity, said first and said second sealing surfaces co-operate to effectively isolate the vestibule from the orifice of the vagina, separately seal off the meatus urinarius, and provide said cavity of said receptacle with a pair of sealing engagements with the female human form firstly around the vestibule of the female human form and secondly around the meatus urinarius of the female human form, thereby permitting urine to freely flow from the urinary bladder into said fluid reservoir without leakage of urine from said receptacle.

17. The combination of claim 16 wherein said hollow stem is radially oriented about said central axis.

18. The combination of claim 16 or claim 17 wherein said hollow stem has a circular cross section and an inner diameter which recedes outwardly and away from said underside of said receptacle opposite said cavity.

19. The combination of claim 15 or claim 18 wherein said pad has attached thereto four stretchable straps.

20. The combination of claim 18 wherein said hollow stem includes a hollow transitional portion being integral therewith, said hollow transitional portion also being integral with a hollow collar, said hollow collar being integral with said underside of said receptacle opposite said cavity.

21. The combination of claim 20 wherein said hollow transitional portion and said hollow collar

are radially oriented about the central axis.

22. The combination of claim 20 or claim 21 wherein said hollow transitional portion and said hollow collar each has a circular cross section, the inner diameter of said hollow collar being greater than the inner diameter of said hollow transitional portion, said inner diameter of said hollow transitional portion being greater than said inner diameter of said hollow stem, said hollow stem having a greater wall thickness than said hollow transitional portion, said hollow transitional portion having a greater wall thickness than said hollow collar.

23. In combination with (a) a urinary appliance adapted to externally sealingly engage a female human form, said appliance having a receptacle containing a cavity, said cavity being radially oriented about a central axis; (b) anti-kinking drainage channel being integral with a backside of said receptacle opposite said cavity and comprising a hollow stem, a hollow transitional portion integral therewith, and a hollow collar integral with said hollow transitional portion, said hollow collar also being integral with said underside of said receptacle opposite said cavity, said hollow stem communicating with said cavity and providing said cavity with an outlet, said hollow stem, said hollow transitional portion, and said hollow collar each being aligned substantially along the direction of said central axis and each having a circular cross section, the inner diameter of said hollow collar being greater than the inner diameter of said hollow transitional portion, said inner diameter of said hollow transitional portion being greater than the inner diameter of said hollow stem, said inner diameter of said hollow stem decreasing progressively receding away from said underside of said receptacle opposite said cavity, said hollow stem having a greater wall thickness than said hollow transitional portion, said hollow transitional portion having a greater wall thickness than said hollow collar; whereupon, when said hollow stem is disposed away from said central axis up to a value of about 90°, said collar along with said transition portion inverts along a portion of their walls with the hollow stem opening into said collar and communication between said cavity and said outlet is maintained.

24. A one piece external female urine collection device adapted to be positioned within the labia folds of the user, adapted to be in contact with the vestibular tissue around the meatus defining the urethral opening and adapted to be held in place by gentle mechanical means and assisted by a controlled vacuum, said device comprising: a generally elliptical and open cup-shaped member having a generally centrally disposed bore opening through said member, an upper surface of said member including a generally elliptical and inwardly-directed close-looped cusped surface and a substantially continuously curved ridge extending upwardly therefrom, surface portions of said upper surface which are disposed away from said cusped

surface opposite said curved ridge and surface portions of said curved ridge defining dual upper portions forming an adjacent pair of sealing surfaces, the inner one of said adjacent surfaces being disposed farther upwardly from said cavity relative to the outer one of said adjacent surfaces, passageway means including a substantially hollow drainage channel integral with said member at a backside thereof, extending therefrom and communicating with said bore opening; and means for preventing said drainage channel from substantially closing and thereby interfering with natural flow or urine from said member, for sealingly and continuously contacting and engaging with the labia folds and said vestibular tissue.

25. A one piece soft and pliable urinary appliance adapted to sealingly engage with the female human form at vestibular surface tissue along underfolds of the labia minora, proximate to the clitoris and proximate to the orifice of the urethra but displaced toward the orifice of the vagina, adapted to receive urinary discharge from a human subject and adapted to be held in place by gentle vacuum, said appliance comprising: a generally ellipsoidal and open-mouthed receptacle including a bore opening through said appliance and said receptacle and a mouth communicating with said bore opening for engaging with said subject at said vestibular tissue, said mouth including a generally elliptical and inwardly-directed close-looped cusped surface and a substantially continuously curved ridge extending upwardly therefrom, surface portions of said mouth which are disposed away from said cusped surface opposite said curved ridge and surface portions of said curved ridge defining two adjacent surfaces of generally outwardly convex curvature surrounding said mouth, the inner one of said adjacent surfaces being disposed farther upwardly from said bore opening relative to the outer one of said adjacent surfaces; passageway means including a substantially hollow cylindrical member integral with said receptacle at a backside thereof, extending generally normally therefrom and communicating with said bore opening; and means for preventing said cylindrical member from substantially closing and thereby interfering with natural flow of urine from said receptacle, for sealingly and continuously contacting and engaging with said vestibular tissue.

26. A female urine collection system comprising: a sealed urine collection vessel having a vessel inlet; a flow control unit including a valve housing defining liquid flow passageway means therethrough having a valve inlet and a valve outlet, and means for controlling a predetermined flow of urine between said valve inlet and said valve outlet and through said housing and for maintaining a preselected vacuum condition at said valve inlet, said collection vessel being in fluid communication with said flow control unit via said valve outlet and providing said predetermined pressure

condition; and, a one piece external female urine collection device adapted to be positioned within the labia folds of the user, adapted to be in contact with the vestibular tissue around the meatus defining the urethral opening and adapted to be held in place by gentle vacuum, said device including a generally elliptical and open cup-shaped member having a generally centrally disposed bore opening through said member, an upper surface of said member including a generally elliptical and inwardly-directed close-looped cusped surface and a substantially continuously curved ridge extending upwardly therefrom, surface portions of said upper surface which are disposed away from said cusped surface opposite said curved ridge defining dual upper portions of a cavity within said member, said dual upper portions forming an adjacent pair of sealing surfaces, the inner one of said adjacent surfaces being disposed farther upwardly from said cavity relative to the outer one of said adjacent surfaces; passageway means including a substantially hollow drainage channel integral with said member at a backside thereof, extending therefrom and communicating with said bore opening, said drainage channel being connected to said valve inlet, said upper surface of said member contacting and engaging with said vestibular tissue, said flow control unit and said urine collection device cooperating to provide said flow control unit with said preselected vacuum condition, said urine collection vessel thereby being in fluid communication with said device through said flow control unit; and means for preventing said drainage channel from substantially closing and thereby interfering with natural flow or urine from said device, for sealingly and continuously contacting and engaging with the labia folds and said vestibular tissue, and for generally uninterruptedly collecting urine in said collection vessel.

27. A female urine collection system comprising: a sealed urine collection vessel having a vessel inlet; a flow control unit including a valve housing defining a valve inlet and a valve outlet and enclosing a flow control element; means for maintaining a predetermined flow of urine between said valve inlet and said valve outlet and through said flow control element and said housing; and means for maintaining predetermined rates of diffusion of gas through at least two different portions of said housing; said collection vessel inlet being connected to said valve outlet; and a one piece soft and pliable urinary appliance adapted to sealingly engage with the female human form at vestibular surface tissue along underfolds of the labia minora, proximate to the clitoris and proximate to the orifice of the urethra but displaced towards the orifice of the vagina, adapted to receive urinary discharge from a human subject and adapted to be held in place by gentle vacuum, said appliance including a generally ellipsoidal and open-mouthed receptacle including a bore opening through said appliance and said receptacle and a

mouth communicating with said bore opening for engaging with said subject at said vestibular tissue, said mouth including a generally elliptical and inwardly-directed close-looped cusped surface and a substantially continuously curved ridge extending therefrom, surface portions of said mouth which are disposed away from said cusped surface opposite said curved ridge and surface portions of said curved ridge defining two adjacent surfaces of generally outwardly convex curvature surrounding said mouth, the inner one of said adjacent surfaces being disposed farther upwardly from said bore opening relative to the outer one of said adjacent surfaces; passageway means including a substantially hollow cylindrical member integral with said receptacle at a back-side thereof, extending generally normally therefrom and communicating with said bore opening, said cylindrical member being connected to said valve inlet, said mouth of said receptacle contacting and engaging with said vestibular tissue, said flow control unit and said urinary appliance cooperating to maintain said predetermined flow of urine between said valve inlet and said valve outlet; and means for preventing said cylindrical member from substantially closing and thereby interfering with natural flow of urine from said receptacle, for sealingly and continuously contacting and engaging with said vestibular tissue for generally uninterruptedly collecting urine in said collection vessel, and for maintaining said predetermined rates of diffusion of said gas.

28. The urine collection system of claim 27 wherein said flow control element is a biasly engageable valve means including a flow control surface and a valve seat for controllably maintaining flow of said urine through said housing.

29. The urine collection system of claim 27 wherein said flow control element is a flapper-type check valve element.

30. The urine collection system of claim 29 wherein said means for maintaining said predetermined flow of said urine and said means for maintaining said predetermined rates of diffusion includes at least one semi-permeable hydrophobic membrane respectively carried along said portions of said housing, at least the downstream one of said portions of said housing including a respective vent hole through said

housing and said at least one membrane respectively engaging therewith such that said urine does not leak therefrom, said at least one membrane having a pore dimension such that said urine does not diffuse therethrough but such that gas is generally permitted to diffuse therethrough.

31. The urine collection system of claim 30 wherein said membranes have a pore dimension of about 3 to 15 microns.

32. The urine collection system of claim 30 wherein said at least one vent hole and hydrophobic membrane are two in number and are provided in said housing both upstream as well as downstream of said flapper valve.

33. A flow control unit comprising: a valve housing defining a valve inlet and a valve outlet and enclosing a flow control element, means for maintaining a predetermined flow of liquid between said inlet and said outlet and through said element and said housing; and means for maintaining predetermined rates of diffusion of gas through at least two different portions of said housing.

34. The flow control unit of claim 33 wherein said flow control element is a biasly engageable valve means including a flow control surface and a valve seat for controllably maintaining flow of said liquid through said housing.

35. The flow control unit of claim 33 wherein said flow control element is a flapper type check valve element.

36. The flow control unit of claim 35 wherein said means for maintaining said predetermined flow of liquid and said means for maintaining said predetermined rates of diffusion includes at least two semi-permeable membranes carried along said portions of said housing, each of said portions of said housing including a respective hole through said housing and said membranes engaging therewith such that said liquid does not leak therefrom, each of said membranes having a pore dimension such that said liquid does not diffuse therethrough but such that gas is generally permitted to diffuse therethrough.

37. The flow control unit of claim 36 wherein said membranes have a pore dimension of about 3 to about 15 microns when said liquid is human urine.